

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 24

REMARKS

Claims 1, 2, 4-6, 8, 11-57, 64, 65, 67-69, 86-94 and 96-115 were pending in the subject application. By this Amendment applicants have canceled claims 2, 4, 31, 36, 50, 55, 68, 86 and 111 without prejudice, and amended claims 1, 21, 28, 33, 38, 42, 47, 52, 56, 64, 65, 88-94, and 101-115. Accordingly, claims 1, 5, 6, 8, 11-30, 32-35, 37-49, 51-54, 56, 57, 64, 65, 67, 69, 87-94, 96-110 and 112-115 are pending and under examination.

This Amendment is in compliance with 37 C.F.R. § 1.116 because it merely incorporated into independent claims the limitations which existed in previously examined dependent and independent claims. Accordingly, this Amendment should be entered.

Furthermore, applicants have filed this Amendment to overcome all of the rejections and objections set forth in the January 30, 2004 Final Office Action, so as to place the claims in condition for allowance pursuant to 37 C.F.R. § 1.116. Specifically, applicants have amended the claims to recite "seed" instead of "storage organ", and to recite specific plants to overcome the enablement rejection. The recitation of specific plants in the amended claims also overcomes the art rejections. Further applicants have amended the claims to specify that the content is increased or decreased, while the composition is modified. This distinction in terminology appears to be clear to the Examiner and, thus, should overcome the indefiniteness rejection.

Applicants specifically address each rejection below.

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 25

Rejections under 35 U.S.C. §112, first paragraph

On page 2 of the January 30, 2004 final Office Action the Examiner rejected claims 110-115 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner alleged that claims 110-115 are directed to the method according to claim 1 in which the total protein nitrogen content of the storage organ of the plant is increased by at least 10%, the total amino acid composition of the storage organ of the plant is increased by at least 8%, the total fiber content of the storage organ of the plant is increased by at least 5%, the total starch content of the storage organ of the plant is increased by at least 10%, the total fatty acid content of the storage organ of the plant is increased by at least 5%, and the content of any one fatty acid in the storage organ of the plant is increased or decreased by at least 5%. The Examiner alleged that these recited limitations do not find support in the specification as originally filed, and thus constitute new matter.

In response, without conceding the correctness of the Examiner's position, but merely to advance prosecution, applicants have canceled claim 111, and amended the claims 110 and 112-115 to recite subject matter that is clearly supported by the specification, e.g. on pages 11-12.

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 26

Rejection under 35 U.S.C. § 112, first paragraph

On pages 3-6 of the January 30, 2004 Final Office Action, the Examiner maintained the rejection of claims 1-2, 4-6, 8, 11-57, 64-65, 67-69, and 96-101, and added a rejection of claims 97-115, under 35 U.S.C. § 112, first paragraph.

Assertions by the Examiner

The Examiner acknowledged that the specification is enabling for a method of increasing the total protein nitrogen content in the seed of a pea, chickpea or rice plant, said method comprising (I) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin operably linked to a promoter sequence capable of conferring expression in a seed, and (ii) determining the content of total protein nitrogen in said seed, a method of increasing the fiber content in the seed of a pea plant, said method comprising (I) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of fiber in said seed, a method of decreasing the fiber content, decreasing the soluble and insoluble non-starch polysaccharide components of fiber, and increasing the lignin component of fiber, in the seed of lupin a plant, said method comprising (I) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content or composition of fiber in said seed, a method of increasing the oil content, and increasing the stearic acid and oleic acid fatty acid components of oil, and decreasing the myristic acid, palmitic acid, linoleic acid, linolenic acid, arachidic acid, gadoleic acid, behenic acid, erucic acid

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 27

and lignoceric acid fatty acid components of oil, in the seed of lupin a plant, said method comprising (I) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of oil in or the fatty acid composition of said seed, a method of decreasing the oil and starch content in the seed of a pea plant, said method comprising (I) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of oil or starch in said seed, a method of increasing the amino acids aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine and methionine in the seed of a pea plant, said method comprising (I) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the amino acid composition of said seed, and a method of increasing the amino acids aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine, methionine, tyrosine, phenylalanine and lysine in the seed of a chickpea plant, said method comprising (I) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the amino acid composition of said seed.

However, the Examiner alleged that the specification does not reasonably provide enablement for methods of modifying the content or composition of any metabolite in any storage organ of any plant by expressing in the storage organ a chimeric gene comprising a nucleotide sequence encoding any sulfur-rich protein operably linked to any promoter, for the reasons of

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 28

record set forth in the office action mailed January 29, 2003. The Examiner noted Applicant's arguments filed July 29, 2003, alleged that they are not persuasive.

The Examiner noted that Applicants argued that because the level of skill in the art of plant molecular biology is high, and the 2S family of proteins is known in the art, and transcriptional regulatory sequences for directing expression in target organs are also known in the art, one of ordinary skill in the art could use known sequences in readily available vectors for the genetic modification of a plant without undue experimentation (reply page 21).

The Examiner did not dispute that the level of skill in the art of plant molecular biology is high, or that the 2S family of proteins is known in the art, or that transcriptional regulatory sequences for directing expression in target organs are also known in the art, but the Examiner maintained that it would require undue experimentation for one of ordinary skill in the art to practice the invention as claimed. The Examiner alleged that the claimed invention is not limited to using known sequences in readily available vectors for the genetic modification of plants, but is directed to using known sequences in readily available vectors for the genetic modification of any plant in order to obtain plants in which the content or composition of fatty acid, starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fiber or total protein nitrogen in any unspecified storage organ of the plant is modified in any unspecified manner. The Examiner noted that the specification provides guidance for using one sequence (encoding sunflower seed albumin) for the

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 29

genetic modification of lupin, pea, chickpea and rice plants to produce plants in which the content or composition of fatty acid, starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fiber or total protein nitrogen in seeds of the plant is modified in a specific manner, depending on the plant species transformed. The Examiner alleged that the specification does not provide guidance with respect to how to use other known sequences to specifically modify the content or composition of the recited metabolites in a plant storage organ, and does not provide guidance with respect to how to use known sequences to specifically modify the content or composition of the recited metabolites in storage organs other than seeds, or in plants species other than those exemplified. The Examiner alleged that such guidance is necessary for enablement because the ability of a nucleotide sequence encoding any sulfur-rich protein from any source, including any 2S protein or the Aspl synthetic protein, to modify the content or composition of any metabolite, including fatty acid, starch, non-starch polysaccharide, insoluble non-starch polysaccharide, fiber and total protein nitrogen, in any storage organ of any species of transgenic plant is unpredictable.

Applicants' Response

In response, to place the subject application in condition for allowance, applicants have amended all pending claims to recite "seed" as the storage organ which the Examiner acknowledged is enabled. Applicants have also specified in the amended claims the modifications which the Examiner acknowledged have been enabled. Finally, applicants have

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 30

specified in the amended claims the plants in which the claimed method is reasonably expected to work.

Applicants' claimed list of plants is not limited to merely the plants used in the examples of the subject application. Rather, applicants are reciting plants that are all of a type in which the claimed method is reasonably expected to work based on the examples with representative plants provided in the specification. Applicants contend that nothing of record adequately supports the enablement rejection of applicants' claims as amended. M.P.E.P. 2164.02.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

On page 6 of the January 30, 2004 final Office Action the Examiner rejected claims 1, 6, 28, 33, 42, 47, 52, 89, 91, 94 and 101 remain rejected and claims 102, 104, 105, 107, 108 and 109 under 35 U.S.C. 112, first paragraph, as allegedly indefinite in the recitation of "modifying" and "modified", for the reasons of record set forth in the office action mailed January 29, 2003.

The Examiner alleged that applicants' arguments filed July 29, 2003 are not persuasive. The Examiner noted that applicants argue that the specification provides various examples of changes that are modifications, and that such changes would be understood in the art as modifications. However, the Examiner maintained the rejection asserting that the examples set forth

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 31

in the specification do not limit the terms "modifying" and "modified" set forth in the rejected claims. The Examiner asserted that the various examples set forth as modifications do not limit the terms "modifying" and "modified" set forth in the rejected claims. The Examiner maintained that the claims encompass any and all modifications in the content or composition of any metabolite in any storage organ of any plant, but alleged that the specification disclosed only specific types of changes in the content or compositions of specific metabolites in the seeds of specific plants. Additionally, newly rejected claims 102, 104, 105, 107, 108 and 109 do not recite any comparative basis for the relative terms "modifying" and "modified".

In response, applicants have amended the claims to clearly recite the intended modifications. The Examiner appears to have appreciated the distinction between the terms "content" and "composition," which terms are defined in the specification. Furthermore, on page 6 of the January 30, 2004 Final Office Action, the Examiner acknowledged that the "specification disclosed only specific types of changes in the content or compositions of specific metabolites in the seeds of specific plants." (Emphasis added). Accordingly, applicants have amended the claims to specify that the content is "increased" or "deceased", while the composition is "modified." The amended claims also recite specific metabolite, and specific plants.

Accordingly, the indefiniteness rejection does not apply to the clarified terminology used in the amended claims.

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 32

The Examiner also rejected claim 65 under 35 U.S.C. 112, second paragraph, as allegedly indefinite in the use of parentheses in line 6, making it unclear whether joba and common bean are meant to be claim limitations.

In response, applicants first note that applicants intended to recite "faba bean" instead of "joba bean", and have done so in the amended claims. Support for the recitation of "faba bean" appears on page 7, line 30 of the specification. Applicants have also eliminated the use of parenthesis in the claims.

The Examiner also rejected claim 103 under 35 U.S.C. 112, second paragraph, as allegedly indefinite in the recitation of "increasing", which the Examiner asserted is a relative term lacking a comparative basis.

In response, applicants have amended claim 103 to provide a comparative basis.

The Examiner also rejected claim 106 under 35 U.S.C. 112, second paragraph, as allegedly indefinite in the recitation of "decreasing", which the Examiner asserted is a relative term lacking a comparative basis.

In response, applicants have amended claim 106 to provide a comparative basis.

The Examiner also rejected claim 111 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite in the recitation of "increased by at least 8%" in reference to "the total amino acid composition". It is unclear how any composition could

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 33

increase, as "composition" refers to amino acid ratios, which may change, but would not increase or decrease.

In response, applicants have canceled claim 111 without prejudice.

Accordingly, applicants respectfully submit that the rejections under 35 U.S.C. § 112, second paragraph, do not apply to the claims as amended and the rejections should be withdrawn.

Rejections under 35 U.S.C. §102(b)

On page 7 of the January 30, 2004 final Office Action the Examiner maintained the rejection of claims 42-44 and 64 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicants IDS), for the reasons of record set forth in the office action mailed January 29, 2003.

The Examiner noted applicants' previous argument, but asserted that Molvig et al. need not explicitly teach such an end result to anticipate the currently rejected claims, as the currently rejected claims are limited to those in which such modifications would merely be an end result of practicing the affirmative method steps set forth in the rejected claims and explicitly taught by Molvig et al namely the expression in seeds of a gene encoding sunflower seed albumin followed by the determination of the amino acid composition of seeds.

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 34

On page 8 of the January 30, 2004 Final Office Action, the Examiner rejected claims 65 and 67-69 under 35 U.S.C. 102(b) as allegedly anticipated by Altenbach et al. (Plant Mol. Biol. 1992 Jan; 18(2):235-45, Applicant's IDS). The Examiner alleged that Altenbach et al. teach transgenic oilseed rape plants expressing in a seed a chimeric gene comprising a nucleotide sequence encoding the brazil nut albumin 2S protein, said sequence operably linked to a promoter capable of conferring expression in a seed, referring to page 238 Figure 1.

Request for Withdrawal of Finality
of January 30, 2004 Office Action

Initially, applicants note that the rejection based on Altenbach et al. has for the first time been set forth in the January 30, 2004 Final Office Action. There was no reason why the rejection based on Altenbach et al. could not have been presented earlier in a complete non-final Office Action. Accordingly, if applicants' amendments to the claims herein do no place the subject application in condition for allowance, applicants respectfully request that the "finality" of the January 30, 2004 Office Action be withdrawn.

Response to Rejections over Molvig et al. and Altenbach et al.

However, applicants believe that the claims as amended herein are in condition for allowance. Specifically, because the amended claims recite specific plants which are neither taught nor suggested by either of Molvig et al. and Altenbach et al., the amended claims are not subject to the stated rejections.

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 35

Accordingly, the rejections under 35 U.S.C. 102 and/or 103 should be reconsidered and withdrawn.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following disclosures, which are listed on Form PTO-1449 (Exhibit A). Copies of the disclosures listed below as items 1-4 are attached hereto as Exhibits 1-4, respectively.

This Information Disclosure Statement is being filed after the issuance of a final Office Action to submit references cited in a March 16, 2004 Supplementary Search Report in the counterpart European application. According to 37 C.F.R. §1.97(d) this Information Disclosure Statement shall be considered if accompanied by the fee set forth in 37 C.F.R. §1.17(p) and a statement under 37 C.F.R. § 1.97(e).

The required fee set forth in 37 C.F.R. §1.17(p) is ONE HUNDRED AND EIGHTY DOLLARS (\$180.00) and a check including this amount is enclosed.

Pursuant to 37 C.F.R. § 1.97(e), applicants state that each item of information contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Supplemental Information Disclosure Statement. Specifically, each item of information contained in this Supplemental Information Disclosure Statement was cited in March 16, 2004

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 36

Supplementary Search Report in the counterpart European application, a copy of which is attached as **Exhibit 5**.

1. Bagga et al., "Coexpression of the Maize δ -Zein and β -Zein Genes Results in Stable Accumulation of δ -Zein in Endoplasmic Reticulum-Derived Protein Bodies Formed by δ -Zein", Plant Cell, American Society of Plant Physiologists, Rockville, MD, US, No. 9, September 1, 1997, pages 1683-1696 (**Exhibit 1**);
2. Denis et al., "Effect of sulphur levels on transgenic double-low *Brassica napus* plants expressing a seed-specific gene encoding a methionine-rich 2S albumin", Plant Breeding, Vol. 115, No. 3, 1996, pages 145-151 (**Exhibit 2**);
3. Saalbach et al., "Stable Expression of the Sulphur-rich 2S Albumin Gene in Transgenic *Vicia narbonensis* Increases the Methionine Content of Seeds", Journal of Plant Physiology, Vol. 145, No. 5-6, 1995, pages 674-681 (**Exhibit 3**); and
4. Waddell et al., "Effect of over-expression on a sulphur rich 2S albumin on the sulphur metabolism of seeds in transgenic *Vicia narbonensis*", Plant Physiology (Rockville), Vol. 114, No. 3 Suppl., 1997, page 302 (**Exhibit 4**).

Applicants respectfully request that the Examiner consider and make of record the references cited in this Information Disclosure Statement.

Applicants: Higgins et al.
Serial No.: 09/508,979
Filed : May 10, 2000
Page : 37

**REVOCATION OF POWER OF ATTORNEY,
APPOINTMENT OF NEW ATTORNEY
AND NOTICE OF NEW CORRESPONDENCE ADDRESS**

With this Amendment applicants are also submitting as **Exhibit 6** a Revocation of Power of Attorney, Appointment of New Attorney And Notice of New Correspondence Address. As requested in the attached document, please forward all future correspondence in connection with the subject application to:

John P. White

Cooper & Dunham LLP

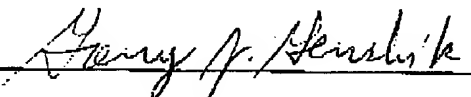
1185 Avenue of the Americas

New York, New York 10036

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$110.00 fee for a one-month extension and a \$180.00 fee for submission of the Information Disclosure Statement is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

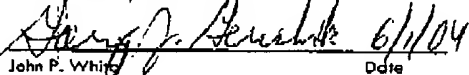
Respectfully submitted,



John P. White
Registration No. 28,678
Gary J. Gershik
Registration No. 39,992
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313-1450.



John P. White
Reg. No. 28,678
Gary J. Gershik
Reg. No. 39,992

Date